



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,876	11/18/2000	John E. Edwards JR.	259/064	7636

34313 7590 04/01/2005

ORRICK, HERRINGTON & SUTCLIFFE, LLP
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
----------	--------------

1645

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/715,876	Applicant(s) EDWARDS ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 9-12 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 9-12 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Request for Continued Examination

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 01/21/05 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 01/21/05 in response to the final Office Action mailed 09/15/04.

Status of Claims

3) Claims 1, 9, 10 and 12 have been amended via the amendment filed 01/21/05.
Claims 1, 3 and 9-12 are pending and are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

6) The objection to the drawing made in paragraph 5 of the Office Action mailed 04/09/03 and maintained in paragraph 7 of the Office Action mailed 02/18/04 and paragraph 5 of the Office Action mailed 09/15/04 is maintained for reasons set forth therein. Applicants have assured the Office that they would submit the formal drawings upon the receipt of the Notice of Allowability.

Rejection(s) Withdrawn

7) The rejection of claim 9 made in paragraph 18(b) of the Office Action mailed 02/18/04 and maintained in paragraph 10 of the Office Action mailed 09/15/04 under 35 U.S.C § 112, second

paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

8) The rejection of claims 1 and 3 made in paragraph 19 of the Office Action mailed 02/18/04 and maintained in paragraph 11 of the Office Action mailed 09/15/04 under 35 U.S.C § 102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998, already of record), is withdrawn in light of Applicants' amendment to claim 1 by including the limitation 'SEQ ID NO: 7'.

9) The rejection of claims 9 and 12 made in paragraph 12 of the Office Action mailed 09/15/04 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to claims.

10) The rejection of claims 10-12 made in paragraph 13 of the Office Action mailed 09/15/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 10.

Rejection(s) Maintained

11) The rejection of claims 10 and 11 made in paragraph 14 of the Office Action mailed 09/15/04 under 35 U.S.C § 102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998, already of record) as evidenced by Harlow *et al.* (*In: Antibodies: A laboratory Manual.* Cold Spring Harbor Laboratory, Chapter 5, p. 76, 1988, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that Hoyer's (1998) prior art product in PBS is not purified, only enriched, because when the N-terminal fragment of ALS1 is dialyzed against PBS, it is clearly part of a mixture of yeast proteins. Applicants submit that Hoyer's later steps of electrophoresis, electroblotting on to a membrane, and N-terminal amino acid sequencing do not constitute the 'biocompatible carrier for injection or infusion, and an isolated and purified N-terminal fragment of agglutinin like sequences (ALS1) cell surface adhesion protein (SEQ ID NO: 7) obtained from *Candida albicans* ...' as recited in claim Applicants' claim 1. Applicants argue that when the Hoyer (1998) ALS1 N-terminal fragment was present with PBS, it was not isolated and purified because unspecified yeast proteins were present. Applicants state that in the further steps required for amino acid sequencing, the Hoyer product was not disclosed as being mixed with PBS, and the Hoyer's preparation was not used as an antigen. Applicants emphasize that the function of ALS1 as an

adhesion protein was not described by Hoyer *et al.* (1998), but by Fu *et al.* (2002). Applicants further submit that the function of the ALS1 protein as an adhesion protein had not been established.

Applicants' arguments have been carefully considered, but are not persuasive. First, the instant rejection was not applied to claim 1, but to claims 10 and 11. Claims 10 and 11 do not structurally identify the recited N-terminal fragment by a SEQ ID number. In other words, instant claims do not place a structural limit on the claimed product. Since the claimed product is not identified by one or more structural limitations, it encompasses Hoyer's fragment or any other purified protein fragment of *Candida albicans*. Instant claims contain a functional limitation without reciting sufficient structure. In the instant case, the only structural limitation that needs to be met by a prior art purified protein is that it must be of *Candida albicans* origin. The functional limitation, on which the prior art reference is silent, is considered as an inherent property inseparable from the prior art protein. Where the only difference between the claimed product and the prior art product is recited in the functional language, i.e., by what it does rather than what it is, it is incumbent upon Applicants, when challenged by the USPTO, to demonstrate that the prior art product does not actually possess those characteristics. For reasons set forth above and those set forth in detail at paragraph 14 of the Office Action mailed 09/15/04, the rejection stands.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

12) Claim 1 and those dependent therefrom are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1, as amended currently, include the limitation: 'the ALS1 protein (SEQ ID NO: 7)'. However, there appears to be no descriptive support in the specification, as originally filed, for a ALS1 protein comprising or consisting of 'SEQ ID NO: 7'. Instead, the amendment introduced 06/21/04 to line 10 of page 6 of the specification identifies 'SEQ ID NO: 7' to be a polynucleotide as opposed to a protein. Therefore, the above-identified limitation in the claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds

after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

13) Claims 1, 3, 9, 11 and 12 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is indefinite, confusing and/or incorrect in the recitation: 'ALS1 protein (SEQ ID No. 7)', because this language is inconsistent with the limitation: 'the nucleotide sequence of SEQ ID NO: 7'. It is unclear how SEQ ID NO: 7 can represent both a protein and a nucleotide sequence.

(b) Claim 12 is indefinite, confusing and/or incorrect in the recitation: 'SEQ ID NO: 7' without specifying that the recited SEQ ID number represents the nucleotide sequence. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the recitation 'SEQ ID NO: 7' with --the nucleotide sequence of SEQ ID NO: 7--.

(c) Claims 9 and 12 lack proper antecedent basis in the limitation: 'ALS1 protein' (see line 2). Claims 9 and 12 depend from claim 1, which already recites an ALS1 protein. For proper antecedence, it is suggested that Applicants provide proper antecedence to the limitation by replacing the limitation with --the ALS1 protein--.

(d) Claim 12 is indefinite and confusing in the limitation: 'nucleotides of SEQ ID NO: 7', because claim 1, from which claim 12 depends, refers to ALS1 protein by SEQ ID NO: 7. It is unclear whether SEQ ID NO: 7 represents a nucleotide sequence or amino acid sequence.

(e) Claims 3 and 9, 11, which depend from claim 1, are also rejected as being indefinite because of the vagueness or indefiniteness identified above in the base claim.

Objection(s)

14) Claims 3 and 11 as well as claims 9 and 12 are duplicate claims encompassing the same scope. Applicants are advised that should claims 3 and 9 be found allowable, claims 11 and 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an

application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Relevant Prior Art

15) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Weinstock *et al.* (US 6,747,137, filed 02/13/1998) disclosed a polypeptide and epitopes thereof encoded by a polynucleotide comprising the amino acid sequence of SEQ ID NO: 2140. Weinstock's SEQ ID NO: 2140 shows 98.5% sequence identity with the polynucleotide having the nucleotide sequence of SEQ ID NO: 7 of the instant application (see entire document).

Remarks

16) Claims 1, 3 and 9-12 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses or papers is (571) 273-8300.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor,

Serial Number: 09/715,876
Art Unit: 1645

Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

March, 2005



S. DEVI, PH.D.
PRIMARY EXAMINER